UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,500	03/07/2005	John P. Wikswo	14506-44191	9498

24728 7590 03/19/2008

MORRIS MANNING MARTIN LLP
3343 PEACHTREE ROAD, NE
1600 ATLANTA FINANCIAL CENTER
ATLANTA, GA 30326

EXAMINER	
RIGGS II, LARRY D	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
03/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,500	WIKSWO ET AL.	
	Examiner	Art Unit	
	LARRY D. RIGGS II	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *17 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *2, 3, 5, 7, 11, 12, 15-27, 29, 30, 32, 38-47, 49, 50, 52 and 57-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6,8-10,13,14,28,31,33-37,48,51 and 53-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12 January 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The art unit and examiner assigned for this application has changed to Examiner Larry D. Riggs II of Art Unit 1631.

Election/Restrictions

It is noted that in the previous Office actions mailed 28 June 2007 and 16 November 2007 inadvertently subjected the instant claims to a restriction requirement under a US only statute 35 U.S.C. §121, when in fact the requirements should have been under a lack of unity requirement encompassing both Restriction is required under 35 U.S.C. 121 and PCT Rule 13.1. However, the groups and species are proper as the claims lack unity for the following reasons: regarding the groups, the controllers could be used to operate the method and the method could be run using different controllers and regarding the species, the types of decision trees are different with different composition and modes of operation, the biological, chemically or neither biological/chemical agents encompass vastly different agents by chemical make-up, characteristics and use, and the conditioned environments comprise unlimited variations or parameters.

Despite the inadvertent restriction requirement under only a US statute, the requirement is considered valid and Applicant's selection of a group and species with traverse will be considered.

Applicant's election with traverse of one species of each of the groups, 1) type of decision tree, (claims 6, 37, 53); 2) type of agent to be discriminated, (claims 4, 8, 31,

51); and 3) type of conditioned environment used, (claims 9-10, 33-34, 54) of the claimed invention in the reply filed on 17 December 2007 is acknowledged.

The traversal is on the ground(s) that Claims 2-5, 29-32 and 49-52 recite different types of agents to be discriminated using the same method as recited in claims 1, 28 and 48, respectively. Claims 7 and 8 recite the same step of selecting logic for classification of a Neuro and Viral different agent, respectively, which is utilized in the method of claim 1. Claims 9, 11 and 12 recite different limitations in the conditioned environment that is utilized in the method of claim 1. Accordingly, Applicant believes that searching the method of claims 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51 and 53-56 with claims 2, 3, 5, 7, 11, 12, 29, 30, 32, 49, 50 and 52 would not impose a serious burden on the Office.

This is not found persuasive because said agents are different and could be interpreted broadly to be most anything, i.e. non-chemical agent or non-biological agent, and be vastly different chemically, characteristics and use. Likewise, the neuro and viral agents have very different characteristics and use. Further, because the various conditioned environments are in contrasting and distinct areas, different methods with different results may apply with the different conditioned environments.

Claims 2, 3, 5, 7, 11, 12, 29, 30, 32, 49, 50, 52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 17 December 2007.

Claims 15-27, 38-47, and 57-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, Group II, in the restriction requirement mailed 28 June 2007, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 27 July 2007.

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

Claims 1-65 are pending. Claims 2, 3, 5, 7, 11, 12, 15-27, 29, 30, 32, 38-47, 49, 50, 52 and 57-65 are withdrawn. Claims 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51 and 53-56 are under consideration.

Claim Objections

Claims 1, 8, 14, 28 and 48 are objected to because of the following informalities:

The MPEP section 608.01(m) states:

While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we) claim," "The invention claimed is" (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the Office of Patent Publication. Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See Fressola v. Manbeck, 36 USPQ2d 1211 (D.D.C. 1995). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i).

In the instant case, claims 1, 14, 28 and 48 provide multiple step identifiers with improperly placed periods.

Appropriate correction is required.

Further, it is noted that Claim 8 provides the capitalized limitation “Viral” in line 2. While not an objection, it is suggested that the limitation be spelled in all lower case as "viral" to be consistent with what the art in the field.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It was not executed in accordance with either 37 CFR 1.66 or 1.68. Two applicants did not provide the date upon signing the declaration.

Specification

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, (see specification, page 4, line 12; page 16, line 4). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The use of the trademarks such as SNAPTIDE and CYTOSENSOR, have been noted in this application, (see specification pages 19 and 32). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51 and 53-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation “one defined action” in lines 2 and 4 of step a) and line 1 of step f). The metes and bounds of the limitation are unclear. The specification and claims do not provide a clear and precise definition of the limitation. One skilled in the art would be unclear as what precise action is referred by the limitation.

Claim 1 recites the limitation "each successive branch corresponding to at least one defined action" in lines 3-4 or step a). The metes and bounds of the limitation are unclear. One skilled in the art would be unclear as whether the "one defined action" in the successive branch is the same defined action or a different defined action from the "one defined action” of each original branch recited in line 2 of step a).

Claim 1 recites the limitation “iteratively repeating steps d)-g) until the agent is discriminated” in line 1 of step h). The metes and bounds of the limitation are unclear.

One skilled in the art would be unclear as to when repeating steps d)-g) would suffice in discrimination of said agent.

Claim 28 recites the limitation "iteratively repeating steps e)-h) until a plurality of classes for the reagent is separated with a desired corresponding confidence level" in lines 1-2 of step i). The metes and bounds of the limitation are unclear. One skilled in the art would be unclear as to when repeating steps e)-h) would suffice with a desired corresponding confidence level.

Claim 48 recites the limitation "iteratively repeating steps f)-i) until a class for the agent with a desired robustness factor is obtained" in lines 1-2 of step j). The metes and bounds of the limitation are unclear. One skilled in the art would be unclear as to when repeating steps f)-i) would suffice with a desired robustness factor being obtained.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51 and 53-56 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a process for discriminating an agent comprising, constructing a decision tree with a plurality of branches, wherein the branches correspond to at least one defined action, providing a conditioned environments sensitive to the agent, obtaining data from response of the agent to the environment, extracting features from the obtained data, selecting a branch from the decision tree

corresponding to the features, performing on the features a defined action corresponding to the branch, producing classification of the agent, iteratively repeating steps until the agent is discriminated.

Since the claimed invention involves mathematical algorithm, which is a judicial exception, the following analysis of facts of this particular patent application follows the rationale suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm).

The Guidelines states:

> *To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):*
>
> *- The claimed invention "transforms" an article or physical object to a different state or thing.*
> *- The claimed invention otherwise produces a useful, concrete and tangible result.*

In the instant claims, there is no physical transformation by the claimed invention because at least one embodiment of the invention could enable all steps of the method to be performed with a computer, wherein the method only designs experimental conditions, obtains data and then classifies an agent based on features of said data, thus the Examiner must determine if the instant claims produce a useful, tangible, and concrete final result.

In determining if the instant claims have a useful, tangible, and concrete final result, the Examiner must determine each standard individually. For a claim to be "useful", the claim must produce a final result that is specific, substantial and credible. For a claim to be "tangible", the claim must set forth a practical application of the invention that produces a real-world final result. For a claim to be "concrete", the process must have a final result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete final result in the claim itself, and the claim must be limited only to statutory embodiments. Thus if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

Method claims 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51 and 53-56 do not produce a tangible final result. A tangible requirement requires that the claim must set forth a practical application of the agent discrimination, to produce a real-world result. The instant claims are drawn to a method of classifying an agent based on data obtained under pre-determined conditions. However, the last step of the claims includes repeating the classification steps of the agent until the agent is discriminated, the result of the invention is a set of data, such as demarcation or identification pertaining to a particular agent, which, in itself, is not tangible. Since the claim itself must include a useful, concrete and tangible final result, the instant claims are non-statutory.

This rejection could be overcome by amendment of the claims to recite that a specific final result of the process is outputted to a user, or by including a result that is a

physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 6, 8-10, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wax (CH2847 IEEE, 1990, 2157-2160) in view of Li et al. (US 6,406,840) and further in view of Whitney (US Pat. Pub. 2002/0159642).

The instant claims are drawn to a method for discriminating an agent, comprising the steps of:

a) constructing a decision tree having a plurality of branches, each branch corresponding to at least one defined action, wherein each branch comprises a plurality of successive branches, each successive branch corresponding to at least one defined action;

b) providing a conditioned environment sensitive to the agent;

c) obtaining data from response of the agent to the conditioned environment;

d) extracting features from the obtained data;

e) selecting a branch from the decision tree corresponding to the features;

f) performing on the features at least one defined action corresponding to the branch;

g) producing a classification of the agent; and

h) iteratively repeating steps of (d)-(g) until the agent is discriminated.

Regarding claim 1, Wax shows a method of constructing a decision tree of structured classifiers, wherein classification is carried out by a sequence of test determined by the path in the tree that the object (agent) to be classified transverses and the path taken from each node depends o the test result obtained at that node (i.e.

leaf), then when a terminal leaf is reached the object is assigned the class-tag associated with that leaf, (see page 2157, right column, paragraphs 4 and 5; Figure 1).

Wax does not show steps b)-d), f) and h), providing a conditioned environment sensitive to the agent, obtaining data from response of the agent to the conditioned environment, extracting features from the obtained data, performing on the features at least one defined action corresponding to the branch and repeating steps d)-g) until the agent is discriminated.

Li et al. shows cell arrays for conducting comparative cell-based analyses, wherein a biological or chemical agent are tested against numerous cell types, (see column 12, line 45 - column 13, line 8; column 16, lines 7-30; Figure 1).

Wax and Li et al. do not show steps d), f) and h), extracting features from the obtained data; performing on the features at least one defined action corresponding to the branch, and iteratively repeating steps of (d)-(g) until the agent is discriminated.

Whitney shows a method for designing algorithms that allow fast retrieval, classification, analysis and processing of data, (see paragraphs [0007-9]; Figure 1 and 5). Whitney shows automated pattern recognition process that may be applied across diverse data types and used in virtually any field, (paragraph [0051]) wherein feature selection performed from any data object or data set, (paragraph [0053-54], [0081[0145]; Figures 7, 8, 14 and 20A-20E). Whitney shows the selection and training of a classifier in order to assign a feature vector extracted form a data object to a particular class, (see [0158]), wherein different classifiers can be used or refined with respect to the feature to classify a data object to a respective class, (see paragraphs

[0068-0076]). Whitney shows a repeated feedback path that allows continually modifying the process and if new feature selection is required, to correctly classify the data object until a stopping condition is met, (see paragraphs [0077-78], [0083-0085]; Figures 1-5).

Regarding claim 4, Li et al. shows testing of a biological agent, (see column 12, lines 26-44).

Regarding claim 6, Wax shows a best split rule of nodes according to the minimum description length principle, (see 2159, left column, paragraphs 1-4).

Regarding claims 8-10, Li et al. shows providing data pertaining to possible viral pathogens associated particular diseases and selecting cell types and exposing selected cell types to a conditioned environment, (see column 12, line 9 - column 13, line 8; column 16, lines 7-30; Figure 1).

Regarding claims 13 and 14, Whitney shows selecting a feature extraction algorithm and classification method (classifier) from a library of algorithms, (see paragraph [0140]), and a plurality of classifications methods, wherein the classifier is applied to the extracted data feature to produce a classification, (see paragraph [0162-0163]).

It would be obvious to one skilled in the arts to modify the method of tree structured classifiers by Wax with the method cellular assays with agent by Li et al. and the methods of feature selection and classification by Whitney because the agent specific data, feature selection of said data and subsequent classification of said

features would be easily implemented in the splitting and pruning rules derived by Wax to better classify an agent of interest, (see Wax, page 2160, last two paragraphs).

Conclusion

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY D. RIGGS II whose telephone number is (571)270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LDR/
Larry D. Riggs II
Examiner, Art Unit 1631

/ Shubo (Joe) Zhou/
Shubo (Joe) Zhou, Ph.D.
Primary Examiner